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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,717	12/14/2001	Guy Michael Miller	346392001500	5287

7590 04/06/2004

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,717	MILLER ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64 and 98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64 and 98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

An Amendment filed January 14, 2004 is acknowledged. Priority documentation is updated. Claims 65-97 are canceled. New claim 98 is presented. Claims 1-64 and 98 are now under consideration.

Declarations of Guy Miller under 37 CFR 1.132 and Sekhar Boddupalli under 37 CFR 1.132 are further acknowledged.

Claims 2, 11-13, 22, 31-33, 42, 53-57 and 98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants state support for "a natural metabolite" is found at page 23, lines 5-14, and Figure 3. A review of those references in the specification fails to disclose a definition of "natural". The term generally would mean nonartificial. With support provides at page 13, lines 9-113, the recitation "naturally occurring" would be given favorable consideration.

Following cancellation of the claims, the rejection of record under 35 U.S.C. 112, second paragraph, is moot.

Claims 3, 5, 7, 8, 24-32, 39-41, and 48-50 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of gamma, beta, delta tocopherols and the single metabolite gamma-CEHC to treat ischemia, does not reasonably provide enablement for any metabolite of gamma, delta or beta tocopherol in the treatment of ischemic conditions.

Applicants assert claims 2, 11-13, 22, 31-33, 42, 53-57, which recite tocopherol-metabolites, may be the claims intended to fall within this rejection. Applicants have advanced arguments under the assumption the asserted claims are those intended to be rejected.

This is not the case. The rejection of claims 3, 5, 7, 8, 24-32, 39-41, and 48-50 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record.

The Boddupalli Declaration has been carefully considered. Through EC_{50} values, both metabolites, gamma-CEHC and delta-CEHC, show significant activity in both the High Glutamate-Induced Oxidative Stress Assay and the MPP+ Assay. However, the declaration is not commensurate in scope with the claims. It is noted there are no beta-tocopherol metabolites in the assays. The 3.0 micromolar value of the gamma tocopherol metabolite 2,3-dimethyl-5-[2-(2-methyl-5-oxo-tetrahydro-furan-2-yl)-ethyl]-[1,4]benzoquinione suggests wide variation among possible metabolites in their activity as affording potential protection against ischemic or hypoxic cell death. A teaching showing or suggesting equivalence among beta, gamma and delta metabolites of tocopherols would be given further consideration.

Claims 1-64 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-62 of co-pending application S.N. 10/020450 in the last Office Action due to overlapping subject matter.

Applicants have elected to hold in abeyance a response to this rejection.

Accordingly, the obviousness-type double patenting rejection is maintained and presently extended to include new claim 98.

Claims 1-7, 14-27, 34-43 and 58-97 were rejected in the last Office Action under 35 U.S.C. 102(e) as being anticipated by Brown et al., U.S. Patent 6,528,042.

In view of the Declaration filed under 37 CFR 1.132 by Dr. Miller, this rejection of record is withdrawn. Dr. Miller states any information that may have been disclosed but not claimed is attributable to Lesley A. Brown and Dr. Guy Miller.

Accordingly, the rejection of record under 35 U.S.C. 102(e) is withdrawn.

Claims 1-64 and 98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitations "a beta-tocopherol enriched tocopherol composition", "a beta-tocopherol metabolite enriched composition", "a delta-tocopherol enriched tocopherol composition", "a delta-tocopherol metabolite enriched composition", "a gamma-tocopherol enriched tocopherol composition" and "a gamma-tocopherol metabolite enriched composition" render the claims in which they appear indefinite. While the presence of a type of tocopherol, i.e., beta, delta or gamma, in the claimed composition is clear, the language of the claims does not preclude other types of tocopherols. Accordingly, the claims lack clarity in that the open language employed permits any other active ingredient including other types of tocopherols. Clarification is required.

Applicants' arguments with respect to claims 41-64 that were rejected in the last Office Action under 35 U.S.C. 103, as being unpatentable over Wechter, WO 00/3544, have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., U.S. 2004/0058987.

Wechter teaches methods for treating and/or ameliorating the symptoms of a cerebral ischemic condition in a mammalian subject comprising administering a non-alpha tocopherol enriched tocopherol composition to reduce neuronal damage related to said cerebral ischemic condition.

Both the claimed compositions and methods of use of Wechter anticipate the presently claimed subject matter.

Claims 41-64 and 98 are rejected under 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., US 2004/0058986.

Wechter teaches methods of treating and/or ameliorating the symptoms of a noncardiovascular tissue ischemic condition comprising administering a gamma-tocopherol enriched tocopherol composition or a gamma-tocopherol metabolite enriched composition. Noncardiovascular tissue ischemic conditions include spinal cord ischemia, liver ischemia, kidney ischemia, peripheral nerve damage and neuropathies.

Both the claimed compositions and methods of use of Wechter anticipate the presently claimed subject matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-64 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter, W.J. US 2004/0029954.

Wechter broadly claims methods of treating or preventing any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which being γ-tocopherol, as well as a metabolite (LLU-α) of gamma-tocopherol. Claimed ischemic conditions include those associated with the liver, the kidney, diabetes, thromboembolic disease, the brain, the nervous system and the eye. The claims differ in that the present claims specify either beta- or delta-tocopherol, as well as reducing cell or tissue death associated with a non-cardiovascular tissue ischemic condition. However, one skilled in the art would have considered the recited compositions, "a beta-tocopherol enriched tocopherol composition", "a beta-tocopherol metabolite enriched composition comprising a metabolite of beta-tocopherol" and "a delta-tocopherol enriched tocopherol composition", "a delta-tocopherol metabolite enriched composition comprising a metabolite of delta-tocopherol" to comprise other tocopherol. The open language of the present claims allows for the addition of any number of other active ingredients in the composition. Further, it would have been reasonable to expect an

improvement in an ischemic condition, i.e., an improvement in blood supply to a bodily organ, would result in a reduction of cell or tissue death associated with ischemia. The determination of optimal concentrations of an active agent is a parameter well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

April 4, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER